

# **EXHIBIT 27**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

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IN RE NATIONAL PRESCRIPTION OPIATE  
LITIGATION

MDL No. 2804

THIS DOCUMENT RELATES TO:

*The County of Summit, Ohio, et al. v. Purdue  
Pharma L.P., et al.*

Case No. 18-OP-45090

*The County of Cuyahoga, Ohio, et al. v. Purdue  
Pharma L.P., et al.*

Case No. 17-OP-45004

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Case No. 17-md-2804

**EXPERT REPORT OF DR. ANUPAM B. JENA, MD, PhD**

May 10, 2019

## I. INTRODUCTION

### A. Qualifications

1. I am the Ruth L. Newhouse Associate Professor of Health Care Policy and Medicine at Harvard Medical School and a physician in the Department of Medicine at Massachusetts General Hospital, the largest affiliated teaching hospital of Harvard Medical School. As a physician, I work as an Internal Medicine Specialist treating patients in the hospital. I treat a wide variety of acute general medical conditions, including cardiovascular diseases such as heart attacks and heart failure; infectious diseases like pneumonia and sepsis; acute complications of liver and kidney disease; complications of substance abuse, including opioids and alcohol; and many other conditions that require inpatient medical care. In my clinical practice I prescribe a broad range of pharmacologic and other therapies and am familiar with how clinical decisions are made regarding treatment. In particular, I routinely prescribe prescription opioid and other analgesic medications to patients with pain in the inpatient setting and, as a prescriber of these medications, I am intimately familiar with the patients who require these treatments, the treatments' indications and contraindications, and how prescribing decisions are made. I also treat patients with opioid use disorder and am familiar with the treatments that are used and, importantly, how this disease impacts people's health and lives. I have a longstanding research focus on opioids that I describe below. I earned my M.D. and Ph.D. in Economics from the University of Chicago and my Bachelors in Biology and Economics from the Massachusetts Institute of Technology.
2. As an economist, I specialize in the economics of physician behavior, the economics of health care productivity, prescription opioid misuse, and the economics of medical innovation. I am a faculty research fellow at the National Bureau of Economic Research, the nation's leading nonprofit economic research organization. I have published nearly 150 peer-reviewed articles in leading medical and economics journals, including the *New England Journal of Medicine*, *Journal of the American Medical Association*, *British Medical Journal*, *Journal of Health Economics*, *Journal of Public Economics*, and *Journal of Economic Perspectives*. From 2014 to 2015, I served on the Institute of Medicine Committee on Diagnostic Errors in Health Care, which was tasked with preparing a follow-on report to the previous highly influential IOM

reports, *To Err is Human* and *Crossing the Quality Chasm*, with the current report focusing on the epidemiology, causes, and policy solutions for diagnostic errors in medicine. In 2016 and 2018, I served on the Centers for Medicare and Medicaid Services (CMS) Technical Expert Panel for episode-based resource use measures, which provided advice to CMS on how to design pay-for-performance measures for individual physicians based on their costs of care when treating patients. Since 2018, I have served on the Advisory Committee on Emerging Science, Technology, and Innovation for the National Academy of Medicine (formerly, the Institute of Medicine). In addition to my academic research, I have consulted for the government, the insurance industry, and pharmaceutical firms on issues related to the economics of pharmaceutical innovation.

3. In addition to my clinical work, I have a longstanding research agenda focused on prescription opioids. I have published multiple studies of prescription opioid misuse in leading journals of medicine and health policy including the *New England Journal of Medicine*, *Journal of the American Medical Association*, *British Medical Journal*, *Annals of Internal Medicine*, and *Health Affairs*. I am among the first researchers to document the widespread variation in opioid prescribing that occurs between hospitals and between individual physicians who practice within hospitals; this research demonstrates the important but under-recognized role that health care providers (both hospitals and physicians) play in driving opioid prescribing. I have studied patterns of misuse of opioids and have performed one of the most comprehensive assessments of how opioid misuse patterns should be measured and how misuse relates to long-term adverse outcomes related to opioids. My research on prescription opioid use in Medicare was also the first to document at a national level the degree to which fragmentation in prescribing of opioids by multiple doctors occurs in the elderly American population and the relationship between fragmented prescribing and downstream adverse patient outcomes. I have also studied the impact of government efforts to reduce opioid prescribing by health care providers, e.g. provider “feedback reports” which aim to reduce opioid prescribing by making providers aware of how often they prescribe opioids relative to peers; the impact of state prescription drug monitoring programs on opioid misuse; and the impact of insurer-led efforts to reduce opioid prescribing, e.g., “quantity limits” on certain prescription opioids. I have also examined the role of illegitimate online pharmacies in contributing to the early stages of the current opioid epidemic. Finally, I was a co-author of the Society of Hospital Medicine’s

clinical guidelines and recommendations for prescribing opioids for acute non-cancer pain in the inpatient setting.

4. In 2007, I was awarded the Eugene Garfield Award by Research America for my work demonstrating the economic value of medical innovation in HIV/AIDS. In 2013, I received the National Institutes of Health Director's Early Independence Award to fund research on the physician determinants of health care spending, quality, and patient outcomes. In 2015, I was awarded the International Society for Pharmacoeconomics and Outcomes Research New Investigator Award. I have lectured internationally and was named one of the 60 Most Powerful People in Health Care in 2016 and one of the 100 Great Leaders in Health Care in 2018 by *Becker's Hospital Review*. My research and scholarly opinions have been published in the *New York Times*, *Washington Post*, *Wall Street Journal*, *Harvard Business Review*, and other places. My curriculum vitae is attached as Appendix A. A list of my testimony in the last four years is contained in Appendix B.

### **B. Assignment**

5. I have been retained by Rite Aid Headquarters Corporation and its affiliated entities, including Rite Aid Mid-Atlantic, to opine on Plaintiffs' methodologies for identifying allegedly suspicious orders distributed by Rite Aid Mid-Atlantic. I understand that pursuant to the Controlled Substances Act and its implementing regulations, distributors of controlled substances are required to "maintain... effective controls against diversion of ... controlled substances ... into other than legitimate medical, scientific, or industrial channels."<sup>1</sup> As part of those controls, distributors are required to "design and operate a system to disclose to the registrant suspicious orders" and to report those orders to the DEA, including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."<sup>2</sup> In addition, I was asked to evaluate Plaintiffs' assessment of alleged harm resulting from Rite Aid Mid-Atlantic's distribution of opioid products. As part of this assignment, I have been asked to consider the opinions of Plaintiffs' experts on these topics,

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<sup>1</sup> 21 USC §823(a)(1); and 21 USC §823(d)(1). See also 21 CFR §1301.71(a) (requiring that distributors "provide effective controls and procedures to guard against theft and diversion of controlled substances.").

<sup>2</sup> 21 CFR §1301.74(b).

#### IV. RITE AID MID-ATLANTIC MAINTAINED SUBSTANTIAL CONTROLS AGAINST DIVERSION OF OPIOIDS

##### A. Rite Aid Mid-Atlantic maintained controls against diversion

33. Plaintiffs claim that distributors, including Rite Aid Mid-Atlantic, failed to maintain effective controls against diversion of opioids. Diversion of opioids occurs when “legally obtained opioids are transferred from a licit to an illicit channel of distribution or use.”<sup>26</sup> In fact, Rite Aid had multiple measures in place to prevent diversion throughout the years at issue, and earlier, and passed numerous inspections conducted by state and federal agencies.<sup>27</sup>
34. One component of maintaining effective controls against diversion is to employ a suspicious order monitoring system (SOM), which Rite Aid Mid-Atlantic did. As an initial matter, it is important to note that the DEA never had explicit requirements for exactly how a suspicious order monitoring system should work and it did not establish a common system across all distributors.<sup>28</sup> As Thomas Prevoznik, Section Chief of Pharmaceutical Investigations at the DEA, testified, there is no one-size-fits-all proposition for SOM systems.<sup>29</sup> Joseph Rannazzisi, former Deputy Assistant Administrator for the Office of Diversion Control at the DEA, noted in his deposition that it was not the DEA’s policy to tell distributors whether an order was suspicious or not, as that was a decision that “only” the distributor could make because they

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<sup>26</sup> Jena, Anupam B., et al., “Opioid Prescribing By Multiple Providers in Medicare: Retrospective Observational Study of Insurance Claims,” *BMJ*, 348:g1393, 2014, p. 2.

<sup>27</sup> Rite\_Aid\_OMDL\_0014804-74, at 05 and 28; Rite\_Aid\_OMDL\_0047171-72; Rite\_Aid\_OMDL\_0032629-33; Rite\_Aid\_OMDL\_0016988-89; Rite\_Aid\_OMDL\_0012516-17; Rite\_Aid\_OMDL\_0032622-28; Rite\_Aid\_OMDL\_0032620; Rite\_Aid\_OMDL\_0032621; Rite\_Aid\_OMDL\_0012547; Rite\_Aid\_OMDL\_0032618-19; Rite\_Aid\_OMDL\_0032614-17; Rite\_Aid\_OMDL\_0036784-87; and Rite\_Aid\_OMDL\_0032612-13.

<sup>28</sup> This notion was confirmed by one of Plaintiffs’ suspicious order monitoring experts in his expert report. Rafalski Report, pp. 12-13 (“Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System (‘SOMS’), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; it is free to design its SOMS using any algorithms and rules it believes will get the job done.”). *See also*, Deposition of Kyle Wright, Unit Chief of the Targeting and Analysis Section at the DEA, February 28, 2019 (hereafter, “Wright Deposition”), pp. 128-129 (“Q. And it was understood, with the move toward the Suspicious Order Monitoring Program, that not every company would necessarily have the exact same type of program; fair? [...] A. Yes, ma’am. Q. And, in fact, DEA wanted companies to be able to adopt their particular programs to whatever the particular clients were that they might service, correct? [...] A. Yes, ma’am.”).

<sup>29</sup> Deposition of Thomas Prevoznik, Section Chief of Pharmaceutical Investigations at the DEA , April 17-18, 2019 (hereafter, “Prevoznik Deposition”), p. 446 (“Q. Is it fair to say that a SOMs systems is not a one-size-all proposition, one-size-fits-all proposition? A. Correct.”).

“know their customer.”<sup>30</sup> Ultimately, it is the DEA’s expectation that each distributor will review its own business model and design a SOM system that fits its specific method of distribution.<sup>31</sup>

35. Rite Aid had multiple anti-diversion measures in place during and prior to the years at issue here. These included inventory control measures, order control and monitoring measures, and an asset protection division.

### **1. Rite Aid Mid-Atlantic’s inventory control measures**

36. Rite Aid Mid-Atlantic’s inventory control measures included the following:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED] <sup>33</sup> [REDACTED]
- [REDACTED] <sup>34</sup>

- Physical inventories of each “pick” location were conducted twice a day (one for the day shift and one for the night shift).<sup>35</sup> Additionally, complete inventories of the

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<sup>30</sup> Deposition of Joseph Rannazzisi, former Deputy Assistant Administrator for the Office of Diversion Control at the DEA, April 26, 2019 (hereafter, “Rannazzisi Deposition”), pp. 42-43 (“Q. And it was DEA’s policy not to tell registrants that an order is or is not suspicious, correct? A. Well, that’s a business decision that only the -- the distributor could make. They’re the only ones who know their customer. And they know what their customers are doing. And they know the -- the population around the customer’s business. They know what is in the area that could warrant an increase or not.”).

<sup>31</sup> Prevoznik Deposition, p. 447 (“Q. And DEA expects that each registrant will review its own business model and design a SOM system that fits its specific method of distribution? [...] A. That’s correct as -- as per the regulations.”).

<sup>32</sup> Deposition of Keith Frost, Department Manager for Pharmacy, Cigarettes, and Centralized Product Departments at Rite Aid Perrymann Distribution Center, January 15, 2019 (hereafter, “Frost Deposition”), pp. 18, 27; Deposition of Larry Ringgold, DEA Coordinator for Security of Rite Aid, January 24, 2019 (hereafter, “Ringgold Deposition”), p. 115.

<sup>33</sup> Ringgold Deposition, pp. 93, 89-90.

<sup>34</sup> [REDACTED]

<sup>35</sup> Frost Deposition, pp. 18-19 (“Q. When you say they pick, what do you mean they pick? A. Our associates get the items and put them in packages or totes to send to our customer stores. Q. So they’re actually picking the items out of some group of inventory to be delivered to the stores? A. Yes, out of forward pick. Q. What’s a forward pick? A. A forward pick is a location where the product is loose in boxes or sometimes it could be cases. It’s an area where, when the orders download, a light lights up. It’s called a pick-to-light system. And a number appears. And that’s what the store wants of that particular item in that particular location. And the

controlled drug cage were also conducted weekly.<sup>36</sup> In the event that a pharmacy reported a shortage in a shipment of controlled drugs, Rite Aid Mid-Atlantic security personnel conducted a thorough investigation, [REDACTED]

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associate goes to that location, look at the number, and puts the item into the tote or box, and then extinguishes the light, and moves onto the next location for the next item that the store wants.”); Deposition of Marian Wood, Former DEA Coordinator at Rite Aid Perryman Distribution Center, January 24, 2019 (hereafter, “Wood Deposition”), pp. 175-176 (“Q. Did you prepare this document, the attachment, the daily inventory forward pick locations chart? A. This is what we used to do our inventory every day. And since it had every SKU, it looks to me like she wanted to see what the limits were for each item. Q. Okay. You said you used it to do your inventory each day. Can you explain how you used this doing your inventory? A. Well, the format is for that. These numbers on the side, this column, would be blank. And then these forms were printed out twice a day, day shift and night shift. And we would do a physical inventory of each pick location. Q. Sorry, when you say ‘this column would be blank,’ you were motioning to the pick limit column? A. I’m sorry, yes. The pick limit column would be the physical inventory column. Q. So you would print this entire spread-sheet every day and use it in your inventory? A. The -- twice a day. I’m assuming this is our entire -- it’s about ten pages, I thought. We would -- a form just like this, that would have every single forward pick location on it, day shift would count every location after every shift, and night shift would do the same. Q. When you say ‘count each location,’ what do you mean by that? A. Count what -- how many -- the physical inventory in that location. Q. So you would go to the physical location of that particular item and see how many were actually in that location, like, meaning on the shelf or in the box or whatever they were held in; is that right? A. Yes.”); Frost Deposition, pp. 77-78 (“Q. Are you aware whether Rite Aid as a registrant was required to provide effective controls against diversion? A. Yes. We always had effective controls against diversion. Q. What’s your understanding of what diversion is? A. Diversion is any theft, misappropriation, misuse of any pharmacy items, which includes control drugs. Not in -- we had procedures, a lot of procedures in place to make sure that didn’t happen. We had SOPs where each associate taking out the trash had to have a lead or a manager inspect for any loose bottles that might have fallen into the trash or got caught up in the -- in the plastic before throwing it away on the conveyor line. Any instances of bottles on -- on the floor, we reported that to the leads and managers [...] both shifts, did a forward pick inventory for everything. And we weren’t really -- we’re not required to do it. There’s nothing in the federal regulations for that. They don’t require biennial inventory or a annual inventory. We did it daily, the forward picks.”).

36 Ringgold Deposition, p. 55.  
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- Investigations were required to be conducted and closed within 48 hours, and security personnel closely tracked and logged details of the investigations.<sup>38</sup>

## 2. Rite Aid Mid-Atlantic's order control and monitoring measures

37. From the late 1990s,<sup>39</sup> including during the period 2006 through 2014 when it ceased distribution of any controlled drugs, Rite Aid Mid-Atlantic's order control and monitoring measures included three key components that prevented shipment of orders of unusual size, frequency, or pattern:

- i. *Shipment Threshold* – Rite Aid Mid-Atlantic employed an order shipment threshold system to control orders. Each order of a controlled drug from a Rite Aid pharmacy to be fulfilled by Rite Aid Mid-Atlantic was subject to a threshold limit unless a pre-existing exception was in place. For virtually all Rite Aid pharmacies supplied by Rite Aid Mid-Atlantic, this limit was 5,000 dosage units per NDC per order.<sup>40</sup> The order threshold system helped ensure that orders were not unusually large because quantities were not shipped above the shipment threshold.
- ii. *Auto Replenishment System (ARS)* – Rite Aid Headquarters Corporation used an ARS to calculate and limit orders from pharmacies through the use of algorithms.<sup>41</sup> The ARS created a suggested order for each pharmacy based on the prior [REDACTED] dispensing

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<sup>38</sup> *Id.*, pp. 48 - 50, 51-52 (“A. Some -- he asked me to keep track and keep him updated weekly on shortage cases [...] Q. Can you explain to me what this particular page represents? A. Weekly investigation tracking sheet, meaning for that week, store numbers, as it explains, dates received, the product, shortage claim, pending date, open or close [...] we had a time limit on trying to close cases. Q. Those would be shortage claim cases? A. Yes. Q. What was the time limit to close those? A. I believe we had 48 hours.”).

<sup>39</sup> Deposition of Janet Getzey Hart, Director of Government Affairs at Rite Aid, January 30, 2019, p. 83.

<sup>40</sup> “Rite Aid of Maryland, Inc.’s Second Supplemental Objections and Answers to Plaintiffs’ First Set of Interrogatories,” January 25, 2019 (hereafter, “Rite Aid’s Second Supplemental Objections (2019)”), p. 13. Between 2006 and 2014, only one store serviced by Rite Aid Mid-Atlantic in Cuyahoga or Summit Counties was permitted an exception to the 5,000 unit threshold rule. Store 3151 was granted an exception to Rite Aid of Maryland’s threshold between 2011 and 2013 with regard to a single hydrocodone combination product and had a higher dosage unit order threshold for that particular product. Even with the exception, the store ordered more than 5,000 units only seven times between 2011 and 2013. See Rite\_Aid\_OMDL\_0012504-05; Rite\_Aid\_OMDL\_0023818; Rite\_Aid\_OMDL\_004657-71; and Rite\_Aid\_OMDL\_0014294.

<sup>41</sup> Rite Aid’s Second Supplemental Objections (2019), p. 15.

history and inventory.<sup>42</sup> Pharmacists could override the suggested order, but only within specific limits.<sup>43</sup> The order could not be more than [REDACTED]

[REDACTED]<sup>44</sup> The ARS thus further ensured that orders were not of unusual size and did not deviate substantially from the normal pattern of ordering.

- iii. *Scheduled Shipments* – The frequency with which pharmacies received shipments was pre-determined and set by Rite Aid Headquarters Corporation and could not be altered by pharmacy personnel. Based on a pharmacy’s size and storage capacity, pharmacies received orders once per week, twice per week, or every other week. The majority of pharmacies received orders once per week.<sup>45</sup> This regular shipment schedule prevented concerns about unusual order frequency.

### 3. Rite Aid’s Asset Protection department

38. In addition, Rite Aid Headquarters Corporation has an “Asset Protection” department. Employees in that department analyze reports and data related to pharmacy orders and did so during the time period that Rite Aid Mid-Atlantic distributed opioids (i.e., before November 2014).<sup>46</sup> Employees reviewed and analyzed Above Average Controlled Drug Purchases reports that compared the amount of controlled substances purchased and dispensed at a pharmacy level.<sup>47</sup> The Asset Protection department also reviewed a set of “key performance indicators” (“KPIs”) relating to pharmacy orders for potential anomalies.<sup>48</sup> If the department detected anomalies in the KPIs, it would initiate an investigation.<sup>49</sup> These investigations could involve a number of additional actions (e.g., installation of additional surveillance cameras) to capture evidence of diversion, with the ultimate possible outcome being reports to law

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<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*, pp. 15-16.

<sup>45</sup> Deposition of Janet Getzey Hart, Director of Government Affairs at Rite Aid, January 31, 2019, pp. 79-80 (“Q. And so orders are placed by Rite Aid stores with a regular frequency. Correct? A. Orders are placed once a week, once every other week in a limited number of stores, and twice a week in a very limited number of stores. Q. So let me break that down. So most -- what most -- what’s the ordering pattern for most stores? A. Most stores, Rite Aid places an order once a week.”).

<sup>46</sup> Rite\_Aid\_OMDL\_0032602.

<sup>47</sup> Rite Aid’s Second Supplemental Objections (2019), p. 16.

<sup>48</sup> *Id.*, p. 16.

<sup>49</sup> *Id.*, p. 16-17.

enforcement and Boards of Pharmacy regarding internal theft and arrest warrants being issued.<sup>50</sup>

**B. Rite Aid Mid-Atlantic's policies and procedures limited the risk of diversion and demonstrated effectiveness**

39. The following five facts documented in this section are consistent with the effectiveness of Rite Aid Mid-Atlantic's previously described anti-diversion measures, its overall policy on the distribution of schedule II drugs, and its distribution structure: Rite Aid Mid-Atlantic (1) passed every state and federal inspection, suggesting the appropriateness of its anti-diversion measures, (2) never distributed schedule II drugs, a more potent class of opioids, (3) distributed only to Rite Aid pharmacies, which permitted an additional layer of monitoring, (4) accounted for less than one percent of opioids distributed to Cuyahoga and Summit Counties, and (5) had stable opioid shipment volumes during the period at issue, despite the fact that total opioid distribution to Cuyahoga and Summit Counties was increasing over the period.

**1. Rite Aid Mid-Atlantic passed every inspection**

40. From 2005-2014, the DEA audited Rite Aid Mid-Atlantic's controls against diversion, including its suspicious order monitoring system, in four unannounced audits and found no deficiencies.<sup>51</sup> Similarly, the State of Maryland performed several inspections of the facility during the relevant time period, including anti-diversion methods, and also found no deficiencies.<sup>52</sup> For example, the State of Maryland's Board of Pharmacy examined Rite Aid Mid-Atlantic's inventory control measures in 2010 and again in 2012 and found that it had a "security system that provides protection against theft and diversion" and an "inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting."<sup>53</sup> In addition, in both inspections, the State of Maryland

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<sup>50</sup> Rite\_Aid\_OMDL\_0037816-51 ("Anatomy of a Pharmacy Case" presentation by Andy Palmer), at 34-48.

<sup>51</sup> Rite\_Aid\_OMDL\_004717-72; Rite\_Aid\_OMDL\_0012516-17; Rite\_Aid\_OMDL\_0032620; Rite\_Aid\_OMDL\_0032618-19; and Rite\_Aid\_OMDL\_0032602. The only recommendations were to "repair wire mesh on cage" and to "add a camera directly over the area where we receive and break down the cage receipts." *See* Rite\_Aid\_OMDL\_0032620.

<sup>52</sup> The only recommendation from the State of Maryland was to identify a carrier tracking number when reporting a vendor shortage. Rite\_Aid\_OMDL\_0032629-33; Rite\_Aid\_OMDL\_0016988-89; Rite\_Aid\_OMDL\_0032622-28; Rite\_Aid\_OMDL\_0032614-17; and Rite\_Aid\_OMDL\_0036784-87.

<sup>53</sup> Rite\_Aid\_OMDL\_0032622-28 at 25; and Rite\_Aid\_OMDL\_0032614-17 at 16.

43. The fact that Rite Aid Mid-Atlantic did not distribute schedule II opioids is relevant, since the schedule III drugs Rite Aid Mid-Atlantic distributed had been considered to have a lower risk of abuse than the schedule II drugs Rite Aid Mid-Atlantic chose not to distribute. For example, a study that surveyed the literature on the comparative abuse potential of hydrocodone and oxycodone found that oxycodone demonstrated higher abuse liability than hydrocodone.<sup>64</sup> Other studies have also found that oxycodone is more commonly abused than hydrocodone. For example, one study found that among opioid-dependent subjects entering a drug treatment program, oxycodone was the drug of choice for significantly more users (44.7 percent) than hydrocodone (29.4 percent).<sup>65</sup> Another study found that among individuals entering treatment for opioid use disorder, more individuals initiated regular opioid use with oxycodone rather than hydrocodone every year from 2006 to 2015.<sup>66</sup>

44. As evidence of the higher potential for abuse, schedule II substances have more stringent prescribing guidelines than schedule III to V substances. While schedule III substance prescriptions can be communicated orally, in writing, or by fax to the pharmacist, schedule II substances require a written prescription signed by the practitioner.<sup>67</sup> In addition, prescriptions for schedule III substances can be refilled up to five times within six months after the date of issue, while the refilling of a prescription for schedule II substances is prohibited.<sup>68</sup>

### **3. Rite Aid Mid-Atlantic distributed to only Rite Aid pharmacies**

45. Rite Aid Mid-Atlantic only distributed to Rite Aid pharmacies, not to clinics, individual practitioners, or non-Rite Aid pharmacies.<sup>69</sup> As a result, Rite Aid Mid-Atlantic distributed to

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<sup>64</sup> Wightman, R. et al., “Likeability and Abuse Liability of Commonly Prescribed Opioids,” *Journal of Medical Toxicology*, Volume 8, 2012, pp. 335-340.

<sup>65</sup> Cicero, Theodore J., et al., “Factors Influencing the Selection of Hydrocodone and Oxycodone as Primary Opioids in Substance Abusers Seeking Treatment in the United States,” *International Association for the Study of Pain*, Vol. 154, December 2013, pp. 2639-2648.

<sup>66</sup> Cicero, Theodore J., et al., “Increased Use of Heroin as an Initiating Opioid of Abuse,” *Addictive Behaviors*, Vol. 74, May 2017, pp. 63-66, at p. 64.

<sup>67</sup> DEA, Diversion Control Division, “Practitioner’s Manual - Section V,” available at <https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm>, accessed May 9, 2019.

<sup>68</sup> *Id.*

<sup>69</sup> Deposition of Christopher Belli, Former Senior Director of Regulatory Compliance and Pharmacy Returns for Rite Aid, December 20, 2018, p. 20 (“Q. Do you understand that DC -- Rite-Aid’s DC 10 [Mid-Atlantic] was a wholesale distributor? Q. To our internal -- they’re inner company sales, so we only ship to our own stores.”).

pharmacies that had in place policies and procedures to prevent diversion.<sup>70</sup> This is not necessarily true of all distributors; many distribute to unaffiliated pharmacies with varying degrees of pharmacy-level policies and procedures.

46. Plaintiffs' experts focus on total distributions of opioids, essentially assuming that every opioid pill sold—whether through a “pill mill” or a Rite Aid pharmacy—had an equivalent chance of diversion (and thus inflicted equal harm). As an expert in medicine, economics, and health policy research, it is my opinion that this assumption is false. Some distribution channels—such as rogue internet pharmacies—had a risk of diversion that was significantly higher than diversion of pills sold through chain pharmacies. Any reliable analysis of the harms caused by distribution of opioids must necessarily consider the varying risks of diversion through different channels of distribution.
47. Rite Aid Mid-Atlantic’s distribution to only Rite Aid chain pharmacies is particularly important since Rite Aid Mid-Atlantic never distributed to rogue Internet-based pharmacies, a well-known channel for diversion of opioids. My own research has examined the rise in popularity of obtaining controlled prescription medications on the Internet without a valid prescription and the necessity of increased efforts to curb illegitimate Internet-based pharmacies.<sup>71</sup> Furthermore, the DEA focused its efforts on rogue Internet pharmacies and rogue pain clinics, to which Rite Aid Mid-Atlantic never distributed.<sup>72</sup> A presentation by the DEA explicitly states that chain pharmacies, such as those to which Rite Aid Mid-Atlantic distributes, are not rogue pharmacies.<sup>73</sup>
48. Rite Aid Mid-Atlantic also never distributed to opioid “pill mills.” Plaintiffs’ expert Dr. Gruber created a database of such prosecutions.<sup>74</sup> Of the 165 total prosecutions, only 23

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<sup>70</sup> See, e.g., Rite\_Aid\_OMDL\_0044309-17 (“Procedures for Validation and Dispensing of High Alert Controlled Substances”); Rite\_Aid\_OMDL\_0044361-62 (memo re: “Validation and Dispensing High Alert Controlled Substances”); Rite\_Aid\_OMDL\_0044387 (“Suspicious DEA Pharmacy Activity” memo).

<sup>71</sup> Jena, et al. (2011); and Jena and Goldman (2011).

<sup>72</sup> Rannazzisi Deposition, p. 197 (“Q. Sir, is it fair that DEA focused its attention in the 2005 to, say, 2009 era on rogue Internet pharmacies? [...] A. I would say the -- up until at least 2008, after the Ryan Hate [sic] Act was passed, it pretty much shut down most of the Internet pharmacies and there was a switch to rogue pain clinics. There has always been rogue pain clinics but the rogue pain clinics got -- increased in numbers quite a bit right after Ryan Hate [sic] was passed.”); and Rannazzisi Deposition, Exhibit 10.

<sup>73</sup> Rannazzisi Deposition, Exhibit 10.

<sup>74</sup> “DOJ Prosecutions of Opioid Pill Mills.xlsx” from backup materials to Gruber Report.

involved establishments categorized as a “pharmacy” and only one of these appear to be related to a national chain pharmacy, which was not Rite Aid.<sup>75</sup> The remaining 142 prosecutions were primarily of clinics and medical offices, i.e. pill mills.<sup>76</sup>

**4. Rite Aid Mid-Atlantic accounts for less than 1% of opioid distribution in Cuyahoga and Summit Counties**

49. Rite Aid Mid-Atlantic distributed a very small share of all opioids into Cuyahoga and Summit Counties. **Exhibit 3** compares the total shipments of opioids to Cuyahoga and Summit Counties with Rite Aid Mid-Atlantic’s shipments.<sup>77</sup> Because opioids differ in potency, shipments are measured in MMEs. Throughout the period January 2006 to December 2014, Rite Aid Mid-Atlantic accounted for 0.71 percent of MMEs distributed into Cuyahoga and Summit Counties. Furthermore, and importantly, Rite Aid Mid-Atlantic’s share of MMEs distributed into the counties declined over time and eventually fell to **zero** after the rescheduling of HCPs to schedule II in October 2014, since Rite Aid Mid-Atlantic stopped distributing HCPs when they became schedule II and stopped distributing all narcotics in November 2014.<sup>78</sup> In contrast, as I discuss below, MMEs dispensed to these counties from other distributors increased during this period.

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<sup>75</sup> The address provided for Eric Tingley is associated with another national chain pharmacy in Connecticut. *Id.*

<sup>76</sup> *Id.*

<sup>77</sup> See ARCOS Data Files. This analysis is limited to observations where the buyer is located in Cuyahoga County or Summit County and the “buyer\_bus\_act” field is not “ANALYTICAL LAB.” Buprenorphine and Methadone are not included in this analysis.

<sup>78</sup> ARCOS Data Files; and Rite\_Aid\_OMDL\_0032602.